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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,809	07/30/2001	Robert David Possee	46309-257438	7430
23594 7590 09/10/2007 JOHN S. PRATT KILPATRICK STOCKTON LLP 1100 PEACHTREE SUITE 2800 ATLANTA, GA 30309			EXAMINER MARVICH, MARIA	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	09/807,809		POSSEE ET AL.	
	Examiner		Art Unit	
	Maria B. Marvich, PhD		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/21/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/23/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-26 and 35-50 have been cancelled. Claims 27-34 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Campos et al (US 6,911,206; see entire document) as evidenced by Kool et al (PNAS, 1994, Vol. 91, pp. 11212-11216). **This rejection is maintained for reasons of record in the office action mailed 2/21/07 and restated below.**

Campos et al teach a method for cloning a gene, wherein the gene encodes a BHV-1 antigen and lutenizing hormone fusion, gD:LH. The method involves providing a naked replication-deficient baculovirus vector and providing pBacHISgd:LH, based upon transfer vector pBacPAK9 that comprises genes that complement for replication deficiency and hence functions as a rescue vector (see col 33, line 35- col 34, line 36). This passage teaches that SF21 insect cells were co-transfected with pBacHISgd:LH and replication deficient baculovirus viral DNA to create a replication deficient baculoviral DNA. Campos et al do not teach any processes of linearization or digestion of the replication deficient baculovirus viral DNA and therefore,

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absent evidence to the contrary, the vector is circular. The art teaches that baculovirus in its wild-type form is circular, (see e.g. Kool et al, page 11212, col 1, ¶ 1). Furthermore, the minimal requirement of this limitation is that the vector can be “kept in state or ready for use”. The vector can be transfected and maintained in bacterial host cells as absent evidence to the contrary, the bacterial host is “capable of being maintained” in a bacterial hosts. Therefore, Campos et al anticipates claims 27-30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campos et al (US 6,911,206; see entire document) as applied to claims 27-30 above, and further in view of Merrington et al (Virology, 1996, pages 338-348; see entire document). **This rejection is maintained for reasons of record in the office action mailed 1/13/06 and 2/21/07 and restated below.**

Applicants claim a method of cloning a gene comprising the steps of providing a naked circular replication-deficient baculovirus vector and a “rescue” vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking in the baculovirus vector such as *lef-2*. The vector is furthermore capable of being maintained in bacteria.

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The teachings of Campos et al are as above except Campos et al do not teach the specific gene that is deficient to render the baculovirus replication deficient.

Merrington et al teach that *lef-2* is a gene that encodes a gene necessary for viral replication (see e.g. page 338, col 2, paragraph 2). Merrington et al teach that the *lef-2* mutation can be "rescued" by co-transfection of unmodified *lef-2*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the replication defective baculovirus vector taught by Campos et al by inactivation of the *lef-2* gene as taught by Merrington et al because Campos et al teach that it is within the ordinary skill of the art to express replication defective baculovirus in a cell and because Merrington teaches that mutation of *lef-2* affects DNA replication. One would have been motivated to do so in order to receive the expected benefit of expected benefit that Merrington et al have defined a gene involved in DNA replication and have demonstrated that a mutation in this gene can be rescued. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 and 103 on pages 4-8 of the amendment filed 6/21/07. Applicants' arguments filed 6/21/07 have been fully considered but they are not persuasive. Applicants' argue essentially that Campos teaches use of a baculovirus BacPAK DNA which is linearized by its commercial supplier. Applicants' support this assertion by arguing that BacPAK recombination sequences are present in the pBAacPAK9 based transfer

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vector so that it can recombine with BacPAK baculovirus DNA and finally the assertion that “The only examples of transfer vectors are pBAacPAK8& 9. This strongly suggests that, as you would expect to use a complementary baculovirus vector, that the baculovirus vector used is pBacPAK6, a linear vector from the same company (Clontech). Linear DNA cannot be used in a one step transfection protocol”. However, these assertion by applicant rely heavily on conjecture and objective reasoning. Guidance for such a situation is found in MPEP 2112 which teaches, “Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.” In response applicants have provided solely objective reasoning,. To this the MPEP 2112 teaches, “[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977))” This was the subject of the interview provided June 12, 2007 and yet applicants have not provided evidence that the prior art reference that the vector of Campos et al is not circular. As the teachings of Campos et al do not lead a person of skill in the art to unequivocally conclude that the “baculovirus viral DNA” cited by Campos et al in col 33 is linear. The MPEP teaches, (see 2144.08) “arguments of counsel cannot take the place of factually supported objective evidence.

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See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)."

As well it is noted that "The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998)". As well, applicants have by recitation in claim 27, step III that the baculovirus vector involved in the recombination reaction is circular clarified that the reaction requires a circular vector. Finally, applicants arguments on page 8 that "it is highly likely that the vector was not replication deficient" is not supported by Campos et al which explicitly states "SF21 cells were co-transfected with pBachHIS-gD:LH and replication deficient baculovirus DNA".

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

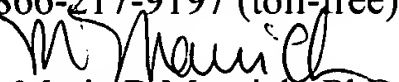
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maria B Marvich, PhD
Examiner
Art Unit 1633

/Joseph Woitach/
Joseph Woitach
SPE 1633